CLAIMS

1. A compound, which is an amorphous form of ziprasidone hydrochloride.

2. The compound of claim 1, having substantially the same X-ray diffraction pattern as shown in Figure 1.

3. The compound of claim 1, wherein said amorphous form of ziprasidone hydrochloride has a moisture content between about 0.5 and about 4.5 % by weight.

4. The compound of claim 1, wherein said amorphous form of ziprasidone hydrochloride has a moisture content between about 3.5 and about 4.5 % by weight.

5. The compound of claim 1, wherein said amorphous form of ziprasidone hydrochloride has a moisture content between about 4.0 and about 4.5 % by weight.

6. A composition comprising ziprasidone hydrochloride as a solid, wherein at least 80 % by weight of said sold ziprasidone hydrochloride is an amorphous form of ziprasidone hydrochloride.

7. The composition of claim 6, wherein at least 90 % by weight of said solid ziprasidone hydrochloride is the amorphous form.

8. The composition of claim 6, wherein at least 95 % by weight of said solid ziprasidone hydrochloride is the amorphous form.

9. The composition of claim 6, wherein at least 99 % by weight of said solid ziprasidone hydrochloride is the amorphous form.

10. The composition of claim 6, wherein said ziprasidone hydrochloride is substantially free of its crystalline Form I.

11. The composition of claim 6, wherein at least 1 % of said solid ziprasidone hydrochloride is not the crystalline Form I.

12. The composition of claim 6, wherein at least 5 % of said solid ziprasidone hydrochloride is not the crystalline Form I.

13. A pharmaceutical composition comprising the compound of claim 1 and one or more pharmaceutically acceptable excipients.

14. The pharmaceutical composition of claim 13, wherein said composition is a solid dosage form for oral administration.

15. The pharmaceutical composition of claim 13, wherein said dosage form is a tablet.

16. A method of treating a psychosis, comprising administering to a patient in need of such treatment an effective amount of the compound of claim 1.

17. A process for making ziprasidone hydrochloride, wherein said process comprising converting ziprasidone to ziprasidone hydrochloride.

18. A process for making an amorphous form of ziprasidone hydrochloride, wherein said process comprising converting ziprasidone to ziprasidone hydrochloride.

19. The process of claim 18, wherein said ziprasidone is a crystalline form, an amorphous form or a mixture thereof.

20. The process of claim 18, wherein said ziprasidone is a crystalline form.

21. The process of claim 18, wherein said ziprasidone is an amorphous form.

22. A process for making an amorphous form of ziprasidone hydrochloride, said process comprising:

a. providing a ziprasidone hydrochloride solution in an aqueous alcoholic solvent;

b. removing said solvent, thereby forming a solid mass; and

c. isolating said solid mass, which is the amorphous form of ziprasidone hydrochloride.

23. The process of claim 22, wherein said aqueous alcoholic solvent is a mixture of water and an alcohol selected from the group consisting of ethanol, methanol, propanol, t-butanol, n-butanol, isopropanol, and mixtures thereof.

24. The process of claim 22, wherein said aqueous alcoholic solvent is a mixture of water and isopropyl alcohol.

25. The process of claim 22, wherein said ziprasidone hydrochloride solution is provided by a process comprising mixing ziprasidone in acetic acid with aqueous hydrochloric acid solution.

26. The process of claim 25, wherein said ziprasidone is a crystalline form, an amorphous form or a mixture thereof.

27. The process of claim 25, wherein said ziprasidone is a crystalline form.

28. The process of claim 25, wherein said ziprasidone is an amorphous form.

29. The process of claim 25, wherein said mixing is done at a temperature between about 30°C and about 70°C.

30. The process of claim 25, wherein said mixing is done at a temperature between about 40°C and about 50°C.

31. The process of claim 25, wherein said process for providing the ziprasidone hydrochloride solution further comprises heating to an elevated temperature.

32. The process of claim 25, wherein said process for providing the ziprasidone hydrochloride solution further comprises heating to reflux temperature.

33. An amorphous form of ziprasidone hydrochloride, which is prepared according to the process of claim 18.

34. An amorphous form of ziprasidone hydrochloride, which is prepared according to the process of claim 22.

35. A compound which is a crystalline form of ziprasidone having an X-ray diffraction pattern, expressed in terms of 2 theta angles, that includes four or more peaks selected from the group consisting of 16.34 ± 0.009, 12.21 ± 0.009, 25.16 ± 0.009, 27.02 ± 0.009, 24.21 ± 0.009, 5.26 ± 0.009 and 18.51 ± 0.009 degrees.

36. The compound of claim 35, having an X-ray diffraction pattern, expressed in terms of 2 theta angles, that includes four or more peaks selected from the group consisting of 16.335, 12.209, 25.156, 27.019, 24.21, 5.255 and 18.511 degrees.

37. The compound of claim 35, having an X-ray diffraction pattern, expressed in terms of 2 theta angles, that includes peaks of 16.335, 12.209, 25.156, 27.019, 24.21, 5.255 and 18.511 degrees.

38. The compound of claim 35, having substantially the same X-ray diffraction pattern as shown in Figure 2.

39. A composition comprising ziprasidone as a solid, wherein at least 80 % by weight of said solid ziprasidone is a crystalline form having an X-ray diffraction pattern, expressed in terms of 2 theta angles, that includes four or more peaks selected from the group consisting of 16.34 ± 0.009, 12.21 ± 0.009, 25.16 ± 0.009, 27.02 ± 0.009, 24.21 ± 0.009, 5.26 ± 0.009 and 18.51 ± 0.009 degrees.

40. The composition of claim 39, wherein at least 90 % by weight of said solid ziprasidone is said crystalline form.

41. The composition of claim 39, wherein at least 95 % by weight of said solid ziprasidone is said crystalline form.

42. The composition of claim 39, wherein at least 99 % by weight of said solid ziprasidone is said crystalline form.

43. A pharmaceutical composition comprising the compound of claim 35 and one or more pharmaceutically acceptable excipients.

44. The pharmaceutical composition of claim 35, wherein said composition is a solid dosage form for oral administration.

45. The pharmaceutical composition of claim 44, wherein said dosage form is a tablet.

46. A method of treating a psychosis, comprising administering to a patient in need of such treatment an effective amount of the compound of claim 35.

47. A process for preparation of a crystalline form of ziprasidone, said process comprising:

a. providing a solution of a salt of ziprasidone in an alcoholic solvent;

b. treating said solution with an aqueous basic solution thereby forming a precipitate; and

c. isolating the precipitate, which is said crystalline form of ziprasidone.

48. The process of claim 47, wherein said salt of ziprasidone is ziprasidone mesylate.

49. The process of claim 48, wherein said ziprasidone mesylate is prepared by a process comprising reacting 6-chloro-5-(2-chloroethyl) oxindole with 3-(1-piperazinyl)-1,2-benzisothiozole.

50. The process of claim 47, wherein said alcoholic solvent is methanol.

51. The process of claim 47, wherein said aqueous basic solution is aqueous caustic lye solution.

52. The process of claim 47, wherein said aqueous basic solution is aqueous sodium hydroxide solution or aqueous potassium hydroxide solution.

53. A pharmaceutical composition comprising the compound of claim 35 and one or more pharmaceutically acceptable excipients.

54. The pharmaceutical composition of claim 53, wherein said composition is a solid dosage form for oral administration.

55. The pharmaceutical composition of claim 54, wherein said dosage form is a tablet.

56. A crystalline form of ziprasidone, which is prepared by the process of claim 47.